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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,908	03/07/2002	Kwang-Soo Kim	04843/097002	2730
21559	7590	07/08/2004		
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			EXAMINER PATTERSON, CHARLES L JR	
			ART UNIT	PAPER NUMBER
			1652	
DATE MAILED: 07/08/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/092,908

Applicant(s)

KIM ET AL.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

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Restriction to one of the following inventions is required under 35

U.S.C. 121:

- I. Claims 1-11 and 14-17 drawn to a method for determining whether a compound is a useful dopamine  $\beta$ -hydrolase inhibitor, classified in class 435, subclass 189.
- II. Claims 12-13, drawn to the method of Group I wherein the compound is useful for congestive heart failure or chronic activation of sympathetic nerve function, classified in class 435, subclass 189 and numerous classes and subclasses in class 424 and 514 depending upon the identity of the inhibitor.
- III. Claim 18, drawn to a polypeptide of SEQ ID NO:38, classified in class 530, subclass 327.
- IV. Claim 18, drawn to a polypeptide of SEQ ID NO:42, classified in class 530, subclass 327.
- V. Claim 18, drawn to a polypeptide of SEQ ID NO:46, classified in class 530, subclass 327.
- VI. Claim 19, drawn to a method for determining whether a patient has an increased risk of miscarriage comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.
- VII. Claim 19, drawn to a method for determining whether a patient has an increased risk of still birth or neonatal death comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.
- VIII. Claim 19, drawn to a method for determining whether a patient has an increased risk of nonadrenergic disease comprising determining

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whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.

- IX. Claim 19, drawn to a method for determining whether a patient has an increased risk of depression comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.
- X. Claim 19, drawn to a method for determining whether a patient has an increased risk of dementia comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.
- XI. Claim 19, drawn to a method for determining whether a patient has an increased risk of bipolar disorder comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.
- XII. Claim 19, drawn to a method for determining whether a patient has an increased risk of schizophrenia comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.
- XIII. Claim 19, drawn to a method for determining whether a patient has an increased risk of attention deficit/hyperactivity disorder comprising determining whether the patient has a mutation in a polynucleotide, classified in class 435, subclass 6.

The inventions are distinct, each from the other because:

Group II involves a treatment method for two different conditions that are not involved in the method of Group I, which is simply a method for determining a dopamine  $\beta$ -hydrolase inhibitor, not involving whether the inhibi-

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tor is useful for treatment. Therefore the two groups are patentably distinct.

Groups III-V are drawn to three different and distinct polypeptides that are not disclosed as being related to any of the other groups. The polypeptides are structurally different and therefore are distinct and properly restricted.

Groups VI-XIII are drawn a method for determining whether a patient has an increased risk for 8 completely different diseases or physiological conditions by seeing if a certain polynucleotide is mutated. This polynucleotide is not claimed in any of the other groups and therefore the method is patentably distinct from any of the other groups. The 8 diseases or conditions are not related and therefore the instant groups are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 571-272-0936. The examiner can normally be reached on Monday - Friday from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-

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0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles L. Patterson, Jr.  
Primary Examiner  
Art Unit 1652

Patterson  
July 6, 2004